



# Potential Utility of Structured Product Labeling v2.0

**HL7 SPL WG**

Friday, March 18, 2005

# Are We Interested in Structured Representations of ??

- Product Labels
- Indications
- Dosing
- Adverse Events
- Monitoring
- Interactions

Yes!!!!

# Quality Matters!

“Conclusions: Patients from the VHA received higher-quality care according to a broad measure.”

Asch et al 12/2004

Annals of Internal Medicine

# VA Health Care

VHA Selected FY 2002 Workloads (Projected) and Comparison to FY 2001 Actuals				
2 projections prior to fiscal year closeout)	FY 2001 Actual	FY 2002 Projected*	Net Change	% Change
Total Enrollees	6,012,773	6,785,441	772,668	12.6
Total Patients Treated (Uniques)**	4,149,706	4,535,575	385,869	9.3
Acute Inpatient Admissions	573,188	564,005	(9,183)	(1.6)
Outpatient Visits (Includes Fee and Readjustment Counseling)	43,808,000	47,323,015	3,515,015	8.0
Nursing Home ADC (All Programs)	31,139	31,606	467	1.5
Rxs Dispensed (30 day equivalent)	167,600,000	175,500,000	7,900,000	4.7
Filled at VAMCs	52,400,000	43,700,000	(8,700,000)	(16.6)
Filled at CMOPs	115,200,000	131,800,000	16,600,000	14.4
Prosthetic Pts. Treated (Not Uniques)	3,993,097	4,472,295	479,198	12.0
Prosthetic Services Performed	5,657,852	6,406,437	748,585	13.2
Prosthetic Expenditures	\$634,663,028	\$699,637,345	\$64,974,317	10.2
Lab Tests (Inpatient and Outpatient)	160,795,166	172,337,117	11,541,951	7.2

\*\*Total Patients Treated excludes CHAMPVA, and Readj. Counseling

October 23, 2001

Office of Policy and Planning (105)

# THE WALL STREET JOURNAL

“In the race to mine medical data, VHA is the unlikely leader. Oft-derided Veterans Health Agency puts Data Online, Saving Time, Lives”

December 10, 2001





# CPRS Integrates Functions

- Order Entry
- Progress Notes
- Problem List
- Clinical Reminders
- Discharge Summary
- Pharmacy
- Radiology
- Laboratory
- Notifications
- Health Summary
- Consult/Request Tracking
- Adverse Reactions

~~Allergies / Adverse Reactions~~

## ~~Postings~~

- Atrial Fibrillation
- Gastritis
- Arrhythmia
- Congestive Heart Failure
- Constipation
- Elevated Psa
- Low Back Pain \* (icd-9-C

Lasix  
Haldol  
Penicillin  
Feathers  
Milk  
Aspirin  
Bee Sting

# Allergies & Adverse Reactions

~~Allergies~~

Pt Has Conservator	Mar 26,01
Clinical Warning	Mar 15,01
Do Not Resuscitate	Mar 02,01
Rx Refill Followup	Sep 29,00
Rx Refill Followup	Sep 27,00
Research Subject	Mar 03,00
Pt Billed Followup	Feb 28,00

## Clinical Reminders

Due Date

No active medications found

V9 Annual/High A1C  
V9 Diabetic Eye Referral  
V9 Depression Screening Positive  
V9 CHF with A-Fib

DUE NOW  
Feb 02,00  
DUE NOW  
DUE NOW

# Problem List

## Vitals

## Postings: Alerts & Warnings

## Medications

## Clinical Reminders

## Appointments

## Recent Labs

### Recent Lab Results

Urinalysis\* Urine Sp Lb #488391 Jan 08

~~capitals~~

P 99.2 F	May 10, 01	(37.3 C)
P 82	May 10, 01	
R 18	May 10, 01	
SP 132/76	May 10, 01	
HT 72 in	May 10, 01	(182.9 cm)
WT 220 lb	May 10, 01	(100.0 kg)

Enter Vitals

~~Appointments / Visits / Admissions~~

Jun 13,01 10:00	Mu-Test	Check
May 23,01 14:44	Kn-Tele Care/Ancillary/Knox	Check
Apr 18,01 09:31	Zzz-ChAkmal(chatt)	Check
Mar 14,01 14:07	Kn-Telephone/Pharmacy/Knox	Check
Jan 31,01 14:30	Na-Telephone Consults/Pharmacy	Check
Jan 22,01 08:30	Mu-2507 Medical Exam Clinic	Check

Cover Sheet Problems Meds Orders Notes Consults D/C Summ Labs Reports Forms



ZTEST\_PATIENT DELTA  
000-00-0004 Dec 07,1899 (101)

Visit Not Selected

Provider: BROWN,STEVEN H

TEST TEAM / Brown,Steven H

Remote  
DataPostings  
WAD

Order Sheet

Active Orders (includes Pending &amp; Recent Activity) - ALL SERVICES

Active Orders (includes Pending &amp; Recent Activity)

Admit...

Write Orders

SERVICE LINE Menus

RETURN TO CLINIC ORDER

Allergies

Diet...

DNR Orders

Nursing Care...

Meds, Inpatient

Meds, Outpatient

IV Fluids...

Lab Tests...

Blood Bank Menu...

Imaging...

Consults/CCR's...

Vitals

Ventilator menu...

Text Only Order

Service	Order	Start / Stop	Provider	Nrs	Clk	C	Sts
Allergy	Reaction to BEE STING	Start: 11/15/00 12:18	Myers,M	LA/W			active
Consults	INTERMEDIATE MEDICINE (019) - NASH Cons Consultant's Choice	Start: 06/11/01 13:24	Smith,L				pendin
	DIABETIC EYE SCREENING CLINIC OPHTHALMOLOGY (031) -NAS Cons Consultant's Choice <CANCELLED BY SERVICE>	Start: 05/09/01 14:22 Stop: 06/14/01 12:07	Karnett,B				cancell
	NUTRITION CONSULT (043) - NASH Cons Consultant's Choice TODAY	Start: 05/09/01 15:21	Abraham,L				pendin
	NUTRITION CONSULT (043) - NASH Cons Consultant's Choice WITHIN 1 WEEK	Start: 04/09/01 15:24	Abraham,L				pendin
Lab	HEMOGLOBIN A1C (NA,MU,CH,CO) BLOOD SP ONCE LB #690714	Start: 05/09/01	Karnett,B				pendin
	HEMOGLOBIN A1C (NA,MU,CH,CO) BLOOD SP ONCE LB #689895	Start: 05/09/01	Wodicka,S				pendin
	HEMOGLOBIN A1C (NA,MU,CH,CO) BLOOD SP LB #631467	Start: 04/05/01	Rodgers,R				pendin
	HEMOGLOBIN A1C (NA,MU,CH,CO) BLOOD SP LB #628337	Start: 04/03/01	Keysaer,S				pendin
	COMPREHENSIVE METABOLIC PANEL (MU,CH) BLOOD SERUM LC LB #604700	Start: 03/20/01 06:30	Smith,L				active
	CBC & DIFFERENTIAL (MU,CH,CO) BLOOD LC ONCE LB #604700	Start: 03/20/01 13:00	Smith,L	NDA			active
	COAGULATION* (PT,INR & aPTT) BLOOD PLASMA LC ONCE LB #604700	Start: 03/20/01 13:00	Smith,L				active
	B12 & FOLATE PANEL (MU,CH) BLOOD SERUM LC ONCE LB #604700	Start: 03/20/01 06:30	Smith,L				active
	TRANSFERRIN* BLOOD SERUM LC ONCE LB #604700	Start: 03/20/01 06:30	Smith,L				active
	COMPREHENSIVE METABOLIC PANEL (NA) BLOOD SERUM SP LB #488320	Start: 01/16/01 10:00	Davis,S				pendin
	LIPID PANEL (NA) BLOOD SERUM SP LB #488320	Start: 01/16/01 10:00	Davis,S				pendin
	URIC ACID (NA,MU,CH,CO) BLOOD SERUM SP ONCE LB #488320	Start: 01/16/01 10:00	Davis,S				pendin
	HEMOGLOBIN A1C (NA,MU,CH,CO) BLOOD SP LB #488320	Start: 01/16/01 10:00	Davis,S				pendin
	CBC & PLT (NA,KX) BLOOD SP LB #488320	Start: 01/16/01 10:00	Davis,S				pendin
	URINALYSIS* URINE SP ONCE LB #488320	Start: 01/16/01 10:00	Davis,S				pendin
	CPK (NA) BLOOD SERUM SP LB #488320	Start: 01/16/01 10:00	Davis,S				pendin
Imaging	CT ABDOMEN W/O CONT	Start: 02/05/01	Witt,W				pendin
	CT CERVICAL SPINE W/CONT	Start: 02/05/01	Witt,W				pendin
	CT CERVICAL SPINE W/O CONT	Start: 02/05/01	Witt,W				pendin
	CT CONTRAST CAT SCAN OF NECK	Start: 02/05/01	Witt,W				pendin

Cover Sheet / Problems / Meds / Orders / Notes / Consults / D/C Summ / Labs / Reports / Forms /

VisiA CPRS in use by: Brown,Steven H (BROKERSERVER)

FileEditViewActionOptionsToolsHelp

ZTEST\_PATIENT DELTA000-00-0004Dec 07,1899 (101)

Visit Not SelectedProvider: BROWN,STEVEN H

TEST TEAM / Brown,Steven H

Remote Data

Postings WAD

Default List

Jun 14,01

PSYCHOLOGY INPATIENT, MU-TEST, JACQUILINE D

Jun 14,01

PSYCHOLOGY INPATIENT, MU-TEST, JACQUILINE D

Jun 14,01

PRIMARY CARE CLINIC (PCC), MU-TEST, Gordon Akin

Jun 13,01

RECREATIO/MUSIC THERAPY AS, MU-TEST, KARLA

Jun 13,01

+ PRIMARY CARE ORDERS, MU-TEST, MARIANNE M

Jun 12,01

TRANSDISCIPLINARY ASSESSMENT, NA-TELEPHON

Jun 12,01

TRANSDISCIPLINARY ASSESSMENT, ZZZ-CH-AKMAI

Jun 11,01

21 DAY CERTIFICATION, MU-2507 MEDICAL EXAM CI

Jun 11,01

21 DAY CERTIFICATION, MU-2507 MEDICAL EXAM CI

Jun 11,01

21 DAY CERTIFICATION, MU-2507 MEDICAL EXAM CI

Jun 11,01

21 DAY CERTIFICATION, MU-2507 MEDICAL EXAM CI

Jun 08,01

MEDICAL STUDENT'S NOTE, KN-TELE CARE/ANCILL

Jun 04,01

PRIMARY CARE ORDERS, KN-TELE CARE/ANCILLAF

May 31,01

+ ATTENDING PHYSICIAN (MEDICINE), KN-TELE CAF

May 24,01

23 HOUR OBSERVATION ADMISSION, KN-TELE CAR

May 23,01

TELEPHONE TRIAGE - KNOXVILLE (TP), KN-TELE CA

May 23,01

WOMENS HEALTH H&P, NA-C&P/ENT, SHAWN P HA

May 22,01

COPC GENERAL, CH-BALLARD(CHATT), ERNEST R F

May 21,01

NUTRITION - NUTRITION SCREENING, MU-2507 MEO

May 10,01

TRANSDISCIPLINARY ASSESSMENT, NA-TELEPHON

May 10,01

ED RECORD - DIET/DIABETES, NA-TELEPHONE COM

May 10,01

+ NURSING GENERAL, BO-BOWLING GREEN/HARRI

May 09,01

NURSING ADMISSION ASSESSMENT, MU-2507 MED

May 09,01

APHERESIS NURSING NOTE, ZZZ-CH-AKMAI(CHATT)

May 09,01

PRIMARY CARE - FOLLOW-UP, ZZZ-CH-AKMAI(CHAT

May 02,01

NURSING NOTE, ZZZ-CH-AKMAI(CHATT), LINDA M K

May 02,01

KNOXVILLE OPC - NURSING ASSESSMENT, ZZZ-CH-

Apr 30,01

23 HOUR OBSERVATION ADMISSION, NA-TELEPHOI

Apr 30,01

NURSING PATIENT ASSESSMENT, ZZZ-CH-AKMAI(C

Apr 30,01

COPC GENERAL, CH-NEW PATIENT(CHATT), Debbie

Apr 26,01

ATTENDING PHYSICIAN ADMISSION NOTE - RESIDE

Apr 25,01

KNOXVILLE OPC - REYNOLDS/COMMUNICATION, KN

Apr 18,01

NURSING GASTROENTEROLOGY, ZZZ-CH-AKMAI(C

Apr 17,01

RETINOPATHY SCREENING, PRIMARY CARE/RES (F

Apr 11,01

MEDICAL STUDENT'S NOTE, CH-BALLARD(CHATT),

Apr 11,01

NURSING PRIMARY CARE ASSESSMENT,, MELANIE

Apr 09,01

ADMISSION CHECK-OFF SHEET - NURSING,, JUNE \

Apr 09,01

NURSING PATIENT CARE RECORD, KN-TELEPHONE

Apr 06,01

NURSING GENERAL, KN-TELEPHONE/PHARMACY/K

Apr 06,01

NURSING GENERAL, KN-TELEPHONE/PHARMACY/K

Apr 05,01

NURSING GENERAL, KN-TELEPHONE/PHARMACY/K

Apr 05,01

NURSING GENERAL, KN-TELEPHONE/PHARMACY/K

Apr 05,01

MENTAL HYGEINE CLINIC - GENERAL NOTE, KN-TEL

Apr 05,01

GENERAL PREVENTIVE MEDICINE, KN-TELEPHONE

New Note

Visit: 06/13/01 PSYCHOLOGY INPATIENT, MU-TEST, JACQUILINE D BETHANY, MS (Jun 14,01@13:21)

TITLE: PSYCHOLOGY INPATIENT

DATE OF NOTE: JUN 14, 2001@13:21

ENTRY DATE: JUN 14, 2001@13:21:26

AUTHOR: BETHANY,JACQUILINE D

EXP COSIGNER: LIMA,PAUL P

URGENCY:

STATUS: COMPLETED

Awake, t and oriented. OOB x 4 today

Up ad lib

ajsldkfalkf

alksjdf laksjdf

weklrjasldk

CAGE ASSESSMENT:

DATE: 06/12/2001

No C felt need to Cut down

No A felt Annoyed by criticism

No C Guilty about drinking

No E ever had an Eye-opener

CAGE ASSESSMENT:

DATE: 06/12/2001

No C felt need to Cut down

No A felt Annoyed by criticism

No C Guilty about drinking

No E ever had an Eye-opener

/es/ JACQUILINE D BETHANY, MS

Psychology Trainee

Signed: 06/14/2001 13:28

/es/ PAUL P LIMA

Staff Psychologist

Cosigned: 06/14/2001 15:08

NEW PATIENT 99201 PROBLEM FOCUSED

Diagnoses: Arrhythmia, Congestive Heart Failure, Constipation (Primary), Elevated Psa, Low Back Pain \* (ICD-9-CM 724.2)

Procedures: Immunization Administer, Single, Immunization, Tetanus(V03.7) - Diagnostic Site To Hospital, VARICELLA VIRUS VAC

Cover SheetProblemsMedsOrdersNotesConsultsD/C SummLabsReportsForms

Start

Dialups

VA programs

CPRS - Patient Chart

7:49 AM



Fall 1999

Spring 2001

Notes

212,000

3,771,583

Orders

1,200,000

10,965,105

CPRS Usage at VA Nashville





# Bar Code Medication Administration

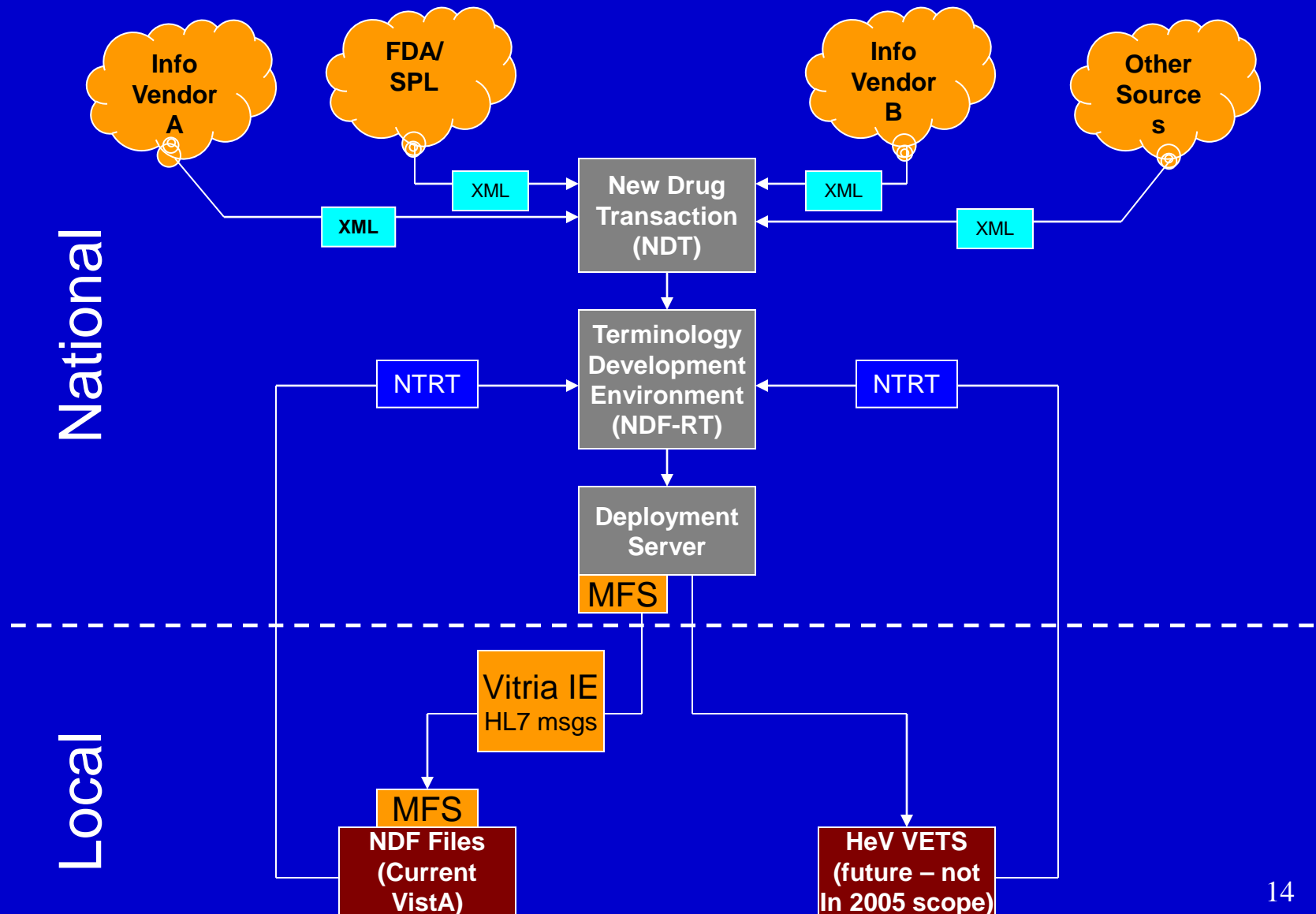
- Extensive Preparations Required at each site
  - Wireless networks on all Wards
  - Bar coded Medications, patients, and nurses
  - Laptops and Scanners
  - Software Deployment



# Looking to the Future

- HealthVet Vista
  - Complete systems redesign to relational database and Java
- Data Standards
  - Standardized data elements across VHA's 128 VistA implementations
  - Happening *Now*
- Abstracted Terminology Services
  - CTS to provide terminology to re-engineered apps

# Hot off the Press for Summer 05 pilot...



# NDF-RT Example

PROPRANOLOL HCL 40MG TAB,UD [NDC: 51079027920]

- Primitive
- Kind: DRUG\_KIND
- Code: C238710
- Id: 238711
- PROPRANOLOL HCL 40MG TAB,UD
- FDA\_Manufacturer: UDL LABORATORIES INC
- FDA\_PackageSize: 100(10 X 10)
- FDA\_PackageType: BOX, UNIT-DOSE
- FDA\_Trade\_Name: PROPRANOLOL HYDROCHLORIDE TABLET
- Level: Packaged Product
- Manufacturer: UDL
- NDC: 51079027920
- NDF\_Trade\_Name: PROPRANOLOL
- PackageSize: 100
- PackageType: UNIT DOSE
- Search\_Name: PROPRANOLOL HCL 40MG TAB,UD [NDC: 51079027920]

PROPRANOLOL HCL 40MG TAB,UD [NDC: 51079027920]

- Primitive
- Kind: DRUG\_KIND
- Code: C238710
- Id: 238711
- PROPRANOLOL HCL 40MG TAB,UD
- some has\_DoseForm: Oral Tablet
- some has\_Ingredient: Propranolol
- some has\_MoA: Adrenergic beta1-Antagonists
- some has\_MoA: Adrenergic beta2-Antagonists
- some has\_PE: Arterial Vasodilation
- some has\_PE: Bronchoconstriction
- some has\_PE: Negative Chronotropy
- some has\_PE: Negative Inotropy
- some may\_treat: Angina Pectoris
- some may\_treat: Anxiety Disorders
- some may\_treat: Esophageal and Gastric Varices
- some may\_treat: Essential Tremor
- some may\_treat: Heart Failure, Congestive
- some may\_treat: Hypertension
- some may\_treat: Hypertension, Portal
- some may\_treat: Migraine
- some may\_treat: Myocardial Infarction
- some may\_treat: Panic Disorder
- some may\_treat: Pheochromocytoma
- some may\_treat: Tachycardia, Supraventricular
- some may\_treat: Tachycardia, Ventricular
- some may\_treat: Ventricular Fibrillation

**Problem List**

SNOMED, incl.

Many procedures w/ mappings prn

Eg ICD9

**Allergies & Adverse Reactions**

Meds as for meds

SNOMED for rxn non-rx reactant

**Postings**

Allergies	
Pt Has Conservator	Mar 26,01
Clinical Warning	Mar 15,01
Do Not Resuscitate	Mar 02,01
Rx Refill Followup	Sep 29,00
Rx Refill Followup	Sep 27,00
Research Subject	Mar 03,00
Rx Refill Followup	Feb 09,00

**Active Medications**

No active medications found

**Medications**

RxNorm, NDF-RT, NDC, UNII, SPL, etc

**Clinical Reminders**

	Due Date
V9 Annual/High A1C	DUE NOW
V9 Diabetic Eye Referral	Feb 02,01
V9 Depression Screening Positive	DUE NOW
V9 CHF with A-Fib	DUE NOW

**Standards ARE Happening in VA!!**

**Document Titles:**  
LOINC

**Recent Lab Results**

Inr - Fingertick (na) Blood, Capillary Sp Lb #587551	Jan 08,01
Urinalysis* Urine Sp Lb #488391	Jan 08,01

**LOINC**

**Vitals**

T	99.2 F	May 10,01	(37.3 C)
P	82	May 10,01	
R	18	May 10,01	
BP	132/76	May 10,01	
HT	72 in	May 10,01	(182.9 cm)
WT	220 lb	May 10,01	(100.0 kg)

**Vitals: SNOMED, cLOINC**

Enter Vitals

**Appointments / Visits / Admissions**

Jun 13,01 10:00	Mu-Test	Checked
May 23,01 14:44	Kn-Tele Care/Ancillary/Knox	CH
Apr 18,01 09:31	Zzz-Ch-Akmal(chatt)	Checked
Mar 14,01 14:07	Kn-Telephone/Pharmacy/Knox	CH
Jan 31,01 14:30	Na-Telephone Consults/Pharm	CH
Jan 22,01 08:30	Mu-2507 Medical Exam Clinic	CH



# Use Scenarios for SPL2 Data

# *Drug Indication Alerts*

A patient with a 10 year history of diabetes is followed in a VA primary care clinic. During a yearly check up the patient is noted to have developed significant spillage of microalbumin into his urine. This lab value is called to the healthcare providers attention, and with one click “diabetic nephropathy” is added to the problem list.

The problem list update triggers a review of VA treatment guidelines and FDA labeling data. The system presents the provider with a “reminder” that VA recommends ACEI use for diabetics with nephropathy.

The reminder displays starting and maintenance dosages of various ACEI's from FDA labeling data for the provider to consider prescribing and a link to the entire label for each.

# *Linking Drugs to Problems for Billing and Other Tracking Purposes*

The problem list update retrieves a mapping of the SNOMED code for Diabetic Nephropathy to ICD9 and places it on the encounter sheet for the visit. Furthermore, the ACEI prescription is also linked to the ICD9 code for billing.

Without automated linking:

15 sec \* 100 million prescriptions = 208 FTEE!!!

# *Drug Adverse Event Alerts*

The same patient with diabetes and diabetic nephropathy returns as an unscheduled patient two weeks later complaining of chronic cough and a change in his ability to taste foods.

The provider, suspecting an adverse drug reaction, requests a patient-specific medication side effect profile from within CPRS. It is immediately clear that the recently prescribed ACEI might account for the new symptoms. After reviewing the relevant full text, the provider decides to hold the medication.

Follow-up 1 week later finds the patient back to baseline.

# *Drugs interfering with Lab Test Alerts*

Several years later, the same diabetic patient develops hypertension that is difficult to control. Interestingly, despite being on an ACEI, his potassium is 2.8. His doctor suspects primary aldosteronism and places a lab order for plasma renin activity and aldosterone concentrations.

The lab orders trigger a medication profile search for FDA documentation of medications that could potential interfere with the lab assays. The provider is advised that ACEI can increase plasma renin activity, and that it is recommended to discontinue ACEI's prior to PRA measurement.

# *Drug Additivity Alerts*

A patient with moderate hypertension treated with metoprolol is noted to have poor blood pressure control at a follow up visit. Her primary care provider elects to start a diuretic to improve control.

Because it sounds like good choice, the provider enters a prescription for “tenoretic 50 mg”. The order entry system immediately notifies the provider that the patient is already receiving a beta blocker.

When the PCP clicks the “more information” button the system responds with a list of products containing chlorthalidone without atenolol, and other products that, like chlorthalidone, decrease intravascular volume and treat hypertension.

# *Medications Indicated for Specific Diseases*

A junior resident diagnoses early Alzheimer's disease in an elderly veteran and is uncertain of current medication options. After the diagnosis is entered into CPRS, the medication ordering system acts as a reference by offering a list of possible medications indicated for its treatment.

All off-formulary meds are grayed out, but on-formulary meds specifically recommended by the VHA Therapeutics Committee appear in bold. She selects several and clicks on More Information to view detailed reference materials, FDA package inserts, and/or commercial drug knowledge bases, to better understand their pros and cons before finally ordering donepezil.

# *Clinical Guideline Reminders*

VHA External Peer Review Program (EPRP) standards require that all non-excluded CAD patients be treated with a aspirin. When a physician views the record of a patient diagnosed with any type of CAD, he is reminded of this guideline if the application determines that the patient is receiving no active medication has that contains aspirin.

A medication pick list with aspirin products can be displayed on demand during this reminder to simplify medication ordering. If the clinician decides to exclude this patient from therapy, he can document his rationale to cancel this reminder for a designated period of time.



# *Updating the Problem List*

After entering the medication order for Ranitidine Bismuth Citrate 400MG TAB in CPRS, a physician is presented with a pick list of its on-label and common off-label indications.

From among several GI diseases, she clicks on Gastroesophageal Reflux (GERD), thereby documenting the therapeutic intent of the prescription and its ICD-9-CM code. Since GERD is a new diagnosis, the patient's Problem List is also updated automatically

# *Data Aggregations for Quality Assurance, Administrative Reporting, or Outcomes Research*

The local chief of cardiology wishes to conduct a study to determine how often beta-adrenergic antagonists are prescribed for patients with myocardial infarction. Their programmer borrows and modifies that EPRP logic to generate aggregate reports based on NDF-RT classes and CPRS data from the local medical center, regional VHA medical centers, and other VHA centers nationwide

# Summary

- VHA is extensively computerized – medical records, order entry, medication administration
- VHA is implementing Standards in accord with CHI commitments
- Structured Product Labels and coded data from FDA is highly desirable for product information distribution and decision support.

The End

